

## PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION  
(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
US Department of Commerce  
United States Patent and Trademark  
Office, PCT  
2011 South Clark Place Room  
CP2/5C24  
Arlington, VA 22202  
ETATS-UNIS D'AMERIQUE  
in its capacity as elected Office

Date of mailing (day/month/year) 14 May 2001 (14.05.01)	
International application No. PCT/US00/00544	Applicant's or agent's file reference FIT-10152/29
International filing date (day/month/year) 10 January 2000 (10.01.00)	Priority date (day/month/year) 18 June 1999 (18.06.99)
Applicant FITZ, William, R.	

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:  
17 January 2001 (17.01.01)

in a notice effecting later election filed with the International Bureau on:  
\_\_\_\_\_

2. The election  was  
 was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Olivia TEFY
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

## PATENT COOPERATION TREATY

PCT

REC'D 15 MAY 2001

WIPO

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference FTT-10152/29	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/00544	International filing date (day/month/year) 10 JANUARY 2000	Priority date (day/month/year) 18 JUNE 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61N 1/34 and US Cl.: 607/46		
Applicant FITZ, WILLIAM R.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

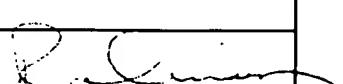
2. This REPORT consists of a total of 4 sheets.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 17 JANUARY 2001	Date of completion of this report 10 APRIL 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer CARL H. LAYNO 
Faxsimile No. (703) 305-3230	Telephone No. (703) 308-3694

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/00544

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

 the international application as originally filed the description:

pages 1-11, as originally filed

pages NONE

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

 the claims:

pages 12-17, as originally filed

pages NONE

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

 the drawings:

pages 1-4, as originally filed

pages NONE

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

 the sequence listing part of the description:

pages NONE, as originally filed

pages NONE

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4.  The amendments have resulted in the cancellation of: the description, pages NONE the claims, Nos. NONE the drawings, sheets/fig NONE5.  This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/00544

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. statement

Novelty (N)	Claims <u>1-27</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-27</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-27</u>	YES
	Claims <u>NONE</u>	NO

## 2. citations and explanations (Rule 70.7)

Claims 1-27 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest method steps for applying pain relieving electrical signals over a medial branch (or articular branch) of a spinal root but whose intensity does not cause a hyperpolarization of the spinal cord (claims 1-13). The claimed methods also apply these electrical signals to peripheral nerves (claim 14) and sciatic nerves (claim 15-27) with the proviso that they too do not cause a hyperpolarization of the spinal cord. The prior art of Feier et al '964 could not be used because of its defective publication date. The other references of record (Barsa '640, Hull et al '719, and Holsheimer et al '703) also describe spinal cord stimulation devices, none of which, however, specifies their electrodes placed adjacent to the medial branch, articular branch, sciatic nerve, or peripheral nerves in the manner claimed by the applicant. No mention is made in any of these references as to the intensity of the electrical pulse applied to their patients' spinal cords. It is unclear whether or not the signals applied meet the criterion of not hyperpolarizing the spinal cord.

----- NEW CITATIONS -----  
NONE

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/00544

## VI. Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication Date (day/month/year)	Filing Date (day/month/year)	Priority date (valid claim) (day/month/year)
US, A, 6,002,964	14 DECEMBER 1999	15 JULY 1998	
US, A, 6,104,957	15 AUGUST 2000	21 AUGUST 1998	
US, A, 6,014,588	11 JANUARY 2000	07 APRIL 1998	

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure  
(day/month/year)Date of written disclosure  
referring to non-written disclosure  
(day/month/year)

**PATENT COOPERATION TREATY**

From the INTERNATIONAL SEARCHING AUTHORITY

To: JOHN G. POSA  
 GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON,  
 & CITOWSKI, PC  
 280 N. OLD WOODWARD AVENUE, SUITE 400  
 BIRMINGHAM, MICHIGAN 48009

*RECEIVED  
MAY 6 2000  
GIFFORD, KRASS, GROH, SPRINKLE,  
ANDERSON & CITOWSKI, PC*

**PCT**

**NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION**

(PCT Rule 44.1)

Date of Mailing  
(day/month/year)

**26 APR 2000**

Applicant's or agent's file reference  
FIT-10152/29

**FOR FURTHER ACTION** See paragraphs 1 and 4 below

International application No.  
PCT/US00/00544

International filing date  
(day/month/year)

10 JANUARY 2000

Applicant  
FITZ, WILLIAM R.

*Response out 5-26-00  
due 6-26-00*

1.  The applicant is hereby notified that the international search report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**  
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO  
 34, chemin des Colombelettes  
 1211 Geneva 20, Switzerland  
 Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2.  The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3.  With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US  
 Commissioner of Patents and Trademarks  
 Box PCT  
 Washington, D.C. 20231  
 Facsimile No. (703) 305-3230

Authorized officer  
CARL H. LAYNO

Telephone No. (703) 308-3694

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: JOHN G. POSA  
 GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON,  
 & CITOWSKI, PC  
 280 N. OLD WOODWARD AVENUE, SUITE 400  
 BIRMINGHAM, MICHIGAN 48009

**PCT**

## NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Date of Mailing  
 (day/month/year)

**26 APR 2000**

Applicant's or agent's file reference  FIT-10152/29	FOR FURTHER ACTION    See paragraphs 1 and 4 below
International application No.  PCT/US00/00544	International filing date (day/month/year) 10 JANUARY 2000
Applicant  FITZ, WILLIAM R.	

1.  The applicant is hereby notified that the international search report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**  
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

**When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

**Where?** Directly to the International Bureau of WIPO  
 34, chemin des Colombettes  
 1211 Geneva 20, Switzerland  
 Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2.  The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3.  With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US  Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231  Facsimile No. (703) 305-3230	Authorized officer  CARL H. LAYNO  Telephone No. (703) 308-3694
---	---

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference FIT-10152/29	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US00/00544	International filing date (day/month/year) 10 JANUARY 2000	(Earliest) Priority Date (day/month/year) 18 JUNE 1999
Applicant FITZ, WILLIAM R.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1.  Certain claims were found unsearchable (See Box I).
2.  Unity of invention is lacking (See Box II).
3.  The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
  - filed with the international application.
  - furnished by the applicant separately from the international application,
    - but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
    - transcribed by this Authority.
4. With regard to the title,  the text is approved as submitted by the applicant.
  - the text has been established by this Authority to read as follows:
5. With regard to the abstract,
  - the text is approved as submitted by the applicant.
  - the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
 

Figure No. 2

  - as suggested by the applicant.
  - because the applicant failed to suggest a figure.
  - because this figure better characterizes the invention.

## Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

## NEW ABSTRACT

Methods, and apparatus are disclosed for stimulating the central, peripheral, autonomic with particular attention being given to the medial branch (210) of the spinal nerve (212) associated with a painful spinal facet joint so as to block pain impulses from reaching the spinal cord. The preferred apparatus includes a neuro-stimulator (204), and two or more electrodes (206) which carry electrical pulses to the target nerves. The impulses are intense enough to cause stimulation of a given medial branch (210), and its articular branches, but not so large as to spread to the spinal cord itself. In the preferred embodiment the stimulator (204) is physically small, and battery operated facilitating implantation underneath the skin. The stimulator (204) includes a controller (not shown), and appropriate electronics operative to generate electrical impulses tailored to an individual's need for appropriate pain relief in terms of pulse frequency, pulse width, and pulse amplitude. In an alternative embodiment, the stimulator (204) further includes electrodes (206), and electrical circuitry operative to monitor myoelectrical activity generated by the surrounding muscles, and modulate the impulses generated by the stimulator to meet the demands of the individual's activity and/or prolong battery life.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/00544

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61N 1/34

US CL : 607/46

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/46

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST, EAST

Search Terms: stimulator, electrodes, spinal nerve, medial, nerve root

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	US 6,002,964 A (FELER et al.) 14 December 1999, Figs. 2, 4, Abstract, col. 6 lines 22-25 and 26-44.	1, 2, 4, 5, 8, 9, 11-13
Y	US 4,570,640 A (BARSA) 18 February 1986, Figs. 1 and 7-15.	1, 3-5, 8, 10, 13
A	US 5,501,703 A (HOLSHEIMER et al.) 26 March 1996, Figs. 1-4A.	1, 2, 7, 8, 11-13
A	US 5,417,719 A (HULL et al.) 23 May 1995, Figs. 1A and 4.	1, 2, 7, 8, 11-13

Further documents are listed in the continuation of Box C.

See patent family annex.

•	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

25 MARCH 2000

Date of mailing of the international search report

26 APR 2000

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

CARL H. LAYNO

Telephone No. (703) 308-3694

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: JOHN G. POSA  
GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON,  
& CITKOWSKI, PC  
280 N. OLD WOODWARD AVENUE, SUITE 400  
BIRMINGHAM, MICHIGAN 48009

**PCT**

## NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)

**11 MAY 2001**

Applicant's or agent's file reference  FIT-10152/29	IMPORTANT NOTIFICATION	
International application No.  PCT/US00/00544	International filing date (day/month/year)  10 JANUARY 2000	Priority Date (day/month/year)  18 JUNE 1999
<p>Applicant  FITZ, WILLIAM R.</p>		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

**R E C E I V E D**  
MAY 16 2001  
GIFFORD, KRASS, GROH, SPRINKLE,  
ANDERSON & CITKOWSKI, PC.

Name and mailing address of the IPEA/US  Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231  Facsimile No. (703) 305-3230	Authorized officer  CARL H. LAYNO  Telephone No. (703) 308-3694
--	---

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: JOHN G. POSA  
GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON,  
& CITOWSKI, PC  
280 N. OLD WOODWARD AVENUE, SUITE 400  
BIRMINGHAM, MICHIGAN 48009

**PCT**

## NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)

**11 MAY 2001**

Applicant's or agent's file reference  FITZ-10152/29	IMPORTANT NOTIFICATION	
International application No.  PCT/US00/00544	International filing date (day/month/year)  10 JANUARY 2000	Priority Date (day/month/year)  18 JUNE 1999
<p>Applicant  FITZ, WILLIAM R.</p>		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US  Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  CARL H. LAYNO
Faxsimile No. (703) 305-3230	Telephone No. (703) 308-3694

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FITZ-10152/29	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/00544	International filing date (day/month/year) 10 JANUARY 2000	Priority date (day/month/year) 18 JUNE 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61N 1/34 and US Cl.: 607/46		
Applicant FITZ, WILLIAM R.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

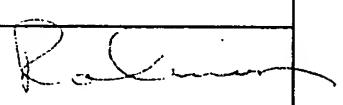
2. This REPORT consists of a total of 4 sheets.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 17 JANUARY 2001	Date of completion of this report 10 APRIL 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer CARL H. LAYNO 
Faxsimile No. (703) 305-3230	Telephone No. (703) 308-3694

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/00544

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

 the international application as originally filed the description:pages 1-11, as originally filed  
pages NONE  
pages NONE, filed with the demand the claims:pages 12-17, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of the drawings:pages 1-4, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of the sequence listing part of the description:pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is: the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4.  The amendments have resulted in the cancellation of: the description, pages NONE the claims, Nos. NONE the drawings, sheets/fig NONE5.  This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/00544

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. statement

Novelty (N)	Claims	1-27	YES
	Claims	<u>NONE</u>	NO
Inventive Step (IS)	Claims	1-27	YES
	Claims	<u>NONE</u>	NO
Industrial Applicability (IA)	Claims	1-27	YES
	Claims	<u>NONE</u>	NO

## 2. citations and explanations (Rule 70.7)

Claims 1-27 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest method steps for applying pain relieving electrical signals over a medial branch (or articular branch) of a spinal root but whose intensity does not cause a hyperpolarization of the spinal cord (claims 1-13). The claimed methods also apply these electrical signals to peripheral nerves (claim 14) and sciatic nerves (claim 15-27) with the proviso that they too do not cause a hyperpolarization of the spinal cord. The prior art of Feier et al '964 could not be used because of its defective publication date. The other references of record (Barsa '640, Hull et al '719, and Holsheimer et al '703) also describe spinal cord stimulation devices, none of which, however, specifies their electrodes placed adjacent to the medial branch, articular branch, sciatic nerve, or peripheral nerves in the manner claimed by the applicant. No mention is made in any of these references as to the intensity of the electrical pulse applied to their patients' spinal cords. It is unclear whether or not the signals applied meet the criterion of not hyperpolarizing the spinal cord.

----- NEW CITATIONS -----  
NONE

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/00544

## VI. Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication Date (day/month/year)	Filing Date (day/month/year)	Priority date (valid claim) (day/month/year)
US, A, 6,002,964	14 DECEMBER 1999	15 JULY 1998	
US, A, 6,104,957	15 AUGUST 2000	21 AUGUST 1998	
US, A, 6,014,588	11 JANUARY 2000	07 APRIL 1998	

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/00544

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61N 1/34

US CL :607/46

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/46

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST, EAST

Search Terms: stimulator, electrodes, spinal nerve, medial, nerve root

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	US 6,002,964 A (FELER et al.) 14 December 1999, Figs. 2, 4, Abstract, col. 6 lines 22-25 and 26-44.	1, 2, 4, 5, 8, 9, 11-13
Y	US 4,570,640 A (BARSA) 18 February 1986, Figs.1 and 7-15.	1, 3-5, 8, 10, 13
A	US 5,501,703 A (HOLSHEIMER et al.) 26 March 1996, Figs. 1-4A.	1, 2, 7, 8, 11-13
A	US 5,417,719 A (HULL et al.) 23 May 1995, Figs.1A and 4.	1, 2, 7, 8, 11-13

Further documents are listed in the continuation of Box C.  See patent family annex.

- \* Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

25 MARCH 2000

Date of mailing of the international search report

26 APR 2000

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

CARL H. LAYNO

Telephone No. (703) 308-3694